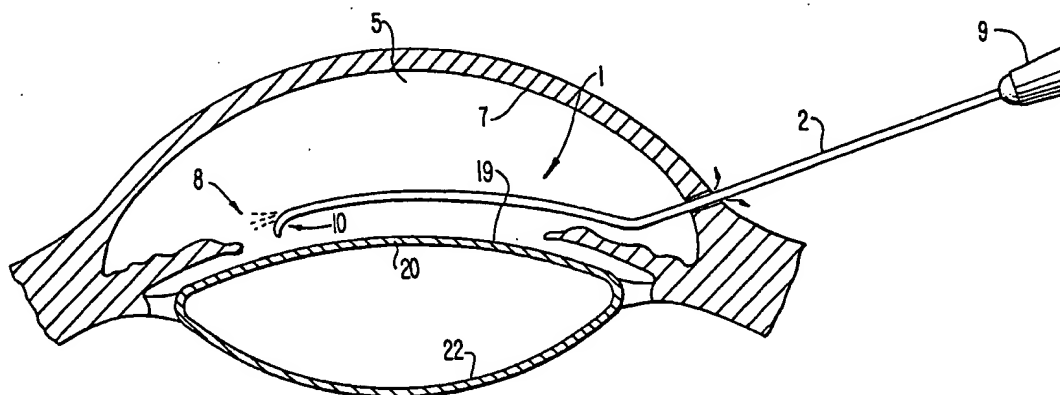




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(21) International Application Number: PCT/US85/02044 (22) International Filing Date: 18 October 1985 (18.10.85) (31) Priority Application Number: 662,624 (32) Priority Date: 19 October 1984 (19.10.84) (33) Priority Country: US (71) Applicant: COOPERVISION, INC. [US/US]; 75 Willow Road, Menlo Park, CA 94025 (US). (72) Inventor: MENDEZ, Antonio ; Post Office Box 925, Calexico, CA 92231 (US). (74) Agents: BOLAND, Thomas, R. et al.; Vorys, Sater, Seymour and Pease, 1828 L Street NW, Suite 1111, Washington, DC 20036-5104 (US).		(81) Designated States: DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP. Published <i>With international search report.</i>

(54) Title: SURGICAL CUTTING INSTRUMENT FOR ULTRASONIC EYE SURGERY



(57) Abstract

A contoured and sharpened needle (1), used for surgical cutting, is formed with a gently curved shaft (2) which matches the surface (19) of the anterior lens capsule (20). The shaft (2) of the needle (1) is bent to provide easy handling of the needle during surgery. Irrigation fluid is delivered through the shaft (2) of the needle (1) to prevent the tip (10) from heating and to minimize trauma to the surrounding tissue. The tip (10) is hook-shaped to allow it to hook and remove the cut anterior capsule (20) once the cutting procedure is finished.

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SURGICAL CUTTING INSTRUMENT FOR ULTRASONIC EYE SURGERYBACKGROUND OF THE INVENTION5 Field of the Invention:

 This invention concerns an ultrasonic cutting device and more particularly concerns a cutting needle designed to match the curve of the surface of the anterior lens capsule for facilitating eye surgery.

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Description of the Prior Art:

 In designing an ultrasonic cutting instrument for performing delicate surgical procedures on the eye, such as, for example, an anterior capsulotomy, it is
15 important that the instrument be shaped to allow a smooth and continuous cutting of the anterior capsule. It is also important to provide some means to minimize the chances for inflicting damage inside the eye, such as that caused through contact of the cutting instrument with the endothelium of the eye. Moreover, it is
20 necessary during such a procedure to avoid the formation of anterior capsule tags.

 One attempt to design an ultrasonic cutting instrument adapted for cataract removal procedures is
25 disclosed by Banko in U.S. Patent No. 3,589,363 wherein a hand-held instrument having an operative tip vibrating at a frequency in the ultrasonic range is designed with various cutting tip configurations shaped according to the particular type of material or tissue to be
30 broken apart or removed. The entire shaft of the cutting tool is disposed in a coaxial relationship with the handle of the cutting tool and therefore is incapable of conforming to the curve of the surface of the anterior lens capsule.

35 Other cutting instruments have been developed in the past but none have met the need for an instrument which will quickly and uniformly cut the anterior

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capsule so as to prevent the formation of loose anterior capsule tags.

SUMMARY OF THE INVENTION

5 Accordingly, this invention has been made to fulfill the needs described above, and therefore has as an important object providing a surgical cutting needle adapted to cut the anterior eye capsule in a very short period of time, for example, within a maximum ultra-
10 sound time period of 20 seconds.

 A further object of the invention is to provide a surgical cutting needle which, when attached to an ultrasonic handpiece such as a Fraxiom® hand-
15 piece, will ensure uniform cutting of the anterior capsule such that loose anterior capsule segments are prevented from being left behind.

 Yet another object is to provide a surgical cutting needle which facilitates the cutting of the anterior capsule in a plurality of shapes, such as
20 circular, square and triangular.

 A still further object of the invention is to provide a surgical cutting needle having a hollow channel formed therethrough for the passage and delivery of irrigation fluid so as to efficiently cool the needle
25 and its cutting tip.

 A further object of the invention is to maintain the depth or shape of the anterior eye chamber with irrigation fluid so as to avoid contact of the surgical cutting needle with the epithelium.

30 Another object is to provide a surgical cutting needle adapted to pull and remove a cut anterior capsule out of the eye after termination of the ultrasound.

 The foregoing and other objects are achieved
35 according to the present invention by the provision of a specially bent and sharpened needle having a gentle curve that matches the surface of the anterior lens

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capsule. Special bends and a sharpened tip provide easy handling of the needle during surgery and help cut the anterior capsule rapidly, uniformly and without leaving anterior capsule tags. Irrigation fluid is delivered through a hole in the tip of the needle to prevent the tip from heating so as to minimize trauma to tissue surrounding the tip and to maintain a deep anterior chamber during the cutting operation.

10 BRIEF DESCRIPTION OF THE DRAWINGS

Various other objects, features and attendant advantages of the present invention will be more fully appreciated as the same becomes better understood from the following detailed description when considered in connection with the accompanying drawings, in which the same reference characters designate like or corresponding parts through the several views. In the drawings:

FIGURE 1 is an elevation view showing the surgical needle attached to a mounting support;

20 FIGURE 2 is an enlarged elevation view of the tip of the needle showing the details of the upturned cutting surface provided adjacent the fluid outlet;

FIGURE 3 is a sectional view of the tip of the needle taken along Line III-III of Figure 1;

25 FIGURE 4 is a sectional view of the needle tip taken along Line IV-IV of Figure 3; and

FIGURE 5 is an elevation view showing the surgical needle in an operative mode wherein the profile of the needle is shown to match the contour of the anterior lens capsule of an eye.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The cutting instrument developed in accordance with the invention will now be described in conjunction with the drawings. Referring first to the Figures 1 and 2, hollow needle 1 is formed with a shaft 2 of, for example, 23 gauge tubular stainless steel,

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thereby defining an internal channel 3 throughout its entire length for the passage of irrigating and/or cooling fluid therethrough.

As shown in Figure 5, irrigating fluid 8 is
5 used to pressurize and maintain the shape and particularly the depth of the anterior chamber 5 of the eye during the cutting operation in order to prevent the needle 1 from touching the endothelium 7 of the anterior chamber 5. The fluid 8 flowing through the needle
10 1 is also used to cool the needle tip 10 so as to minimize trauma to the tissue surrounding the cut formed with the sharpened needle tip and to minimize heating of such tissue.

The needle 1 may be mounted upon a needle
15 support 9 adapted for attachment to an ultrasonic source by, for example, screw threads 11. The needle support 9 may be formed with flat surfaces 13 for engagement with a tool for torquing the needle support 9 into a handpiece. The handpiece typically houses an
20 ultrasonic generator for powering the needle. An important feature of needle 1 is the formation of bend 15 at a point approximately midway between needle tip 10 and the point of attachment 16 of needle shaft 2 to the needle support 9. Bend 15 may extend within an
25 angle A from approximately 10 to 75 degrees, although a bend of 35 degrees has been found to be preferable.

The distal portion 17 of the needle 1 which extends from bend 15 to tip 10 is gently curved along surface 21 to match or complement the surface 19 of
30 anterior lens capsule 20 as shown in Figure 5. The base portion 18 of needle 1 extends from bend 15 to attachment point 16 on needle support 9. It has been found that distal portion 17 may extend over a length of approximately one half inch and may be formed with a
35 radius of curvature of approximately 1.0 to 1.5 inches to suitably conform to the surface profile 19 of the anterior capsule 20. In this manner, contact with the

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endothelium 7 is minimized so as to prevent injury thereto. The gentle curve defined by contoured surface 21 allows a more uniform cut to be made as compared with needles lacking bend 15 and lacking the gentle curve defined by surface 21.

As shown in greater detail in Figures 2, 3 and 4, the distal portion 17 of the hollow needle shaft 2 is formed with a turned or hooked tip 10 defining a saddle-shaped surface portion 23. Saddle 23 may be formed with a radius of curvature R of approximately 0.010 to 0.020 inch to form a hook-shaped tip 10 for hooking and removing the cut anterior capsule once the cutting procedure is finished. The hooked tip 10 is formed from the homogeneous tubular stock material of shaft 2 to facilitate manufacture. It has been found advantageous to round off tip sections 25 and 27 with chamfer radii of approximately 0.020 to 0.025 and 0.012 to 0.018 inch respectively. Flat surface portions 29 are formed between rounded tip sections 25 and 27 at the exit point of the channel 3 and may extend over a length of, for example, 0.010 to 0.040 inch.

As more clearly shown in Figure 4, a concave surface 31 is formed between the flat surface portions 29. Concave surface 31 is formed beneath or opposite saddle surface 23 and gradually diminishes in depth with respect to flat surfaces 29 as needle tip 10 tapers towards its apex 33. It has been found advantageous to turn or hook tip 10 through an angle B defined between flat surfaces 29 and cutting edges 35. A preferred value for angle B is 60 degrees.

As shown in Figure 2, apex 33 is provided with a chamfer radius 34 ranging from, for example, 0.002 to 0.004 inch. As depicted in Figure 4, apex 33 is included within an angle C of approximately 10 degrees and is defined between lateral tip surfaces 37 to form a wedge-shaped tip. In addition, apex 33 is further included within an angle E of approximately 15°

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so as to define a double tapered tip. Lateral tip surfaces 37 can be seen to taper inwardly from the sharp cutting edges 35 through angle C thereby defining edges 35 as chisel-shaped cutting edges. Tip apex 33 is further seen in Figure 3 wherein sharp linear cutting edges 35 are shown to taper toward tip 33 to form a compound or faceted wedge-shaped tip included within an angle D of approximately 40 degrees thereby forming compound angled surfaces along tip 10. Surfaces 29, 35 and 37 may be formed by grinding.

Edges 35 are designed to effect a clean, fast and uniform cut of the anterior capsule 20. When needle support 9 is attached to an ultrasonic vibrator and subjected to a power of, for example, 6 to 9 watts, the tip 10 will enable the anterior lens capsule 20 to be quickly and uniformly cut. Irrigation fluid 8 is delivered through channel 3 to prevent the tip 10 from heating and to maintain a deep and pressurized anterior chamber 5 during a surgical procedure. By keeping the cutting tip 10 cool, damage to the anterior chamber 5 of the eye is prevented. Most of the vibration along shaft 2 occurs at bend 15. Longitudinal movement of the distal end 17 with respect to the base portion 18 and the support 9 is reduced through the formation of bend angle A thereby allowing just enough vibration to transform the needle 1 into an extremely sharp knife which uniformly cuts the anterior capsule 20.

The gentle curve 21 formed on the distal portion 17 of the needle 1 is dimensioned to match the anterior surface 19 of the anterior lens capsule 20. This gentle curve facilitates smooth and continuous cutting of the anterior lens capsule 20 so as to expedite all cutting procedures.

Accordingly, the bend 15, gentle curved section 21 and the sharpened tip 10 provide easy handling of the needle 1 during surgery and help cut the anterior capsule quickly, easily, uniformly, and without

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leaving anterior capsule tags. It has been found that actual cutting time may be limited to 20 seconds. The bent or hooked tip 10 may then be used to hook, pull and remove the cut anterior capsule 20 out of the eye after the ultrasonic cutting power has been turned off.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

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WHAT IS CLAIMED IS:

1. A surgical cutting instrument comprising:
a shaft having a base portion and a
distal portion, said distal portion forming a bend
5 angle with said base portion; and
a cutting tip formed on said distal
portion.
2. The instrument of Claim 1 wherein said
distal portion comprises an arcuate profile correspond-
10 ing to a surface to be cut.
3. The instrument of Claim 1 wherein said
shaft comprises a hollow tubular shaft having a channel
formed therein for the passage of fluid therethrough.
4. The instrument of Claim 1 wherein said tip
15 comprises a hooked tip.
5. The instrument of Claim 1 wherein said tip
comprises an arcuate saddle-shaped section.
6. The instrument of Claim 1 wherein said bend
angle comprises an angle of approximately 35°.
- 20 7. The instrument of Claim 1 wherein said tip
comprises at least one sharp cutting edge.
8. The instrument of Claim 7 wherein said at
least one sharp cutting edge comprises a first sharp
cutting edge and a second sharp cutting edge, said
25 first and second sharp cutting edges tapering toward
the apex of said tip.
9. The instrument of Claim 1 wherein said
angle is formed at approximately the longitudinal mid-
point of said shaft.
- 30 10. A surgical cutting instrument, comprising:
a shaft having a longitudinal axis,
said shaft formed with a curved section along said
longitudinal axis and having a cutting tip provided
thereon.
- 35 11. The instrument of Claim 10 wherein said
curved section corresponds to an arcuate surface pro-
file of an anterior capsule of an eye lens.

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12. The instrument of Claim 10 wherein said shaft comprises a hollow tubular shaft having a channel formed therein for the passage of fluid therethrough.

13. The instrument of Claim 12 wherein said
5 hollow shaft defines an outlet adjacent said tip for the exit of fluid therefrom.

14. The instrument of Claim 10 wherein said cutting tip comprises first and second cutting edge portions.

10 15. The instrument of Claim 14 wherein said first and second cutting edge portions taper toward said tip to define a wedge-shaped tip.

16. The instrument of Claim 10 wherein said tip
15 comprises an arcuate saddle-shaped surface portion defining a hook-shaped tip.

17. The instrument of Claim 16 wherein said tip further comprises a concave surface portion opposite said saddle-shaped surface portion.

18. The instrument of Claim 17 wherein said
20 shaft comprises a hollow tubular shaft defining an outlet adjacent said tip.

19. The instrument of Claim 10 wherein said cutting tip and said shaft are formed homogeneously from tubular stock material.

25 20. A method for cutting the anterior capsule of an eye comprising:

providing a surgical cutting instrument comprising a shaft having a base portion and a distal portion, said distal portion forming a bend angle with said base portion;
30 and a cutting tip formed on said distal portion;

applying to said base portion ultrasonic vibrations directed along said shaft, whereby said cutting tip is vibrated ultrasonically, and

35 applying said ultrasonically vibrating cutting tip to said anterior capsule and drawing it across said capsule, whereby a smooth cut is made in said capsule.

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FIG. 1.

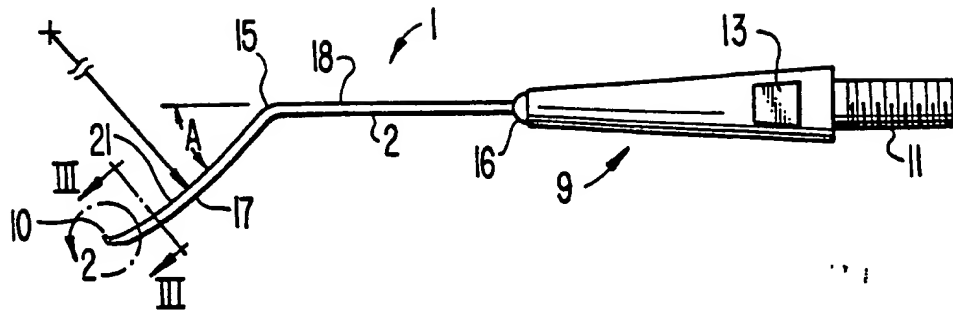


FIG. 2.

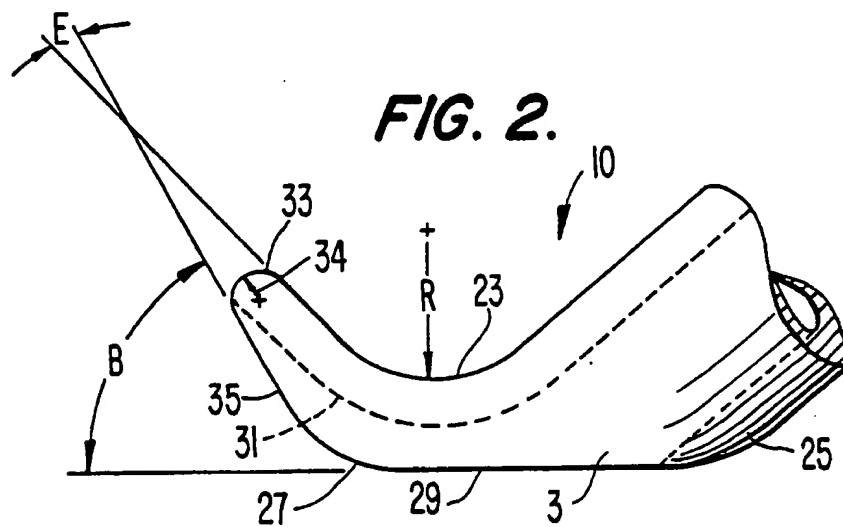


FIG. 3.

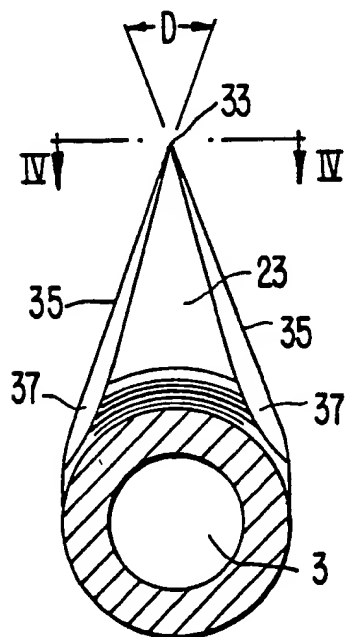
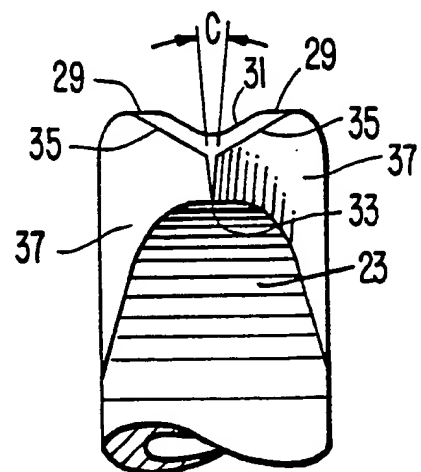
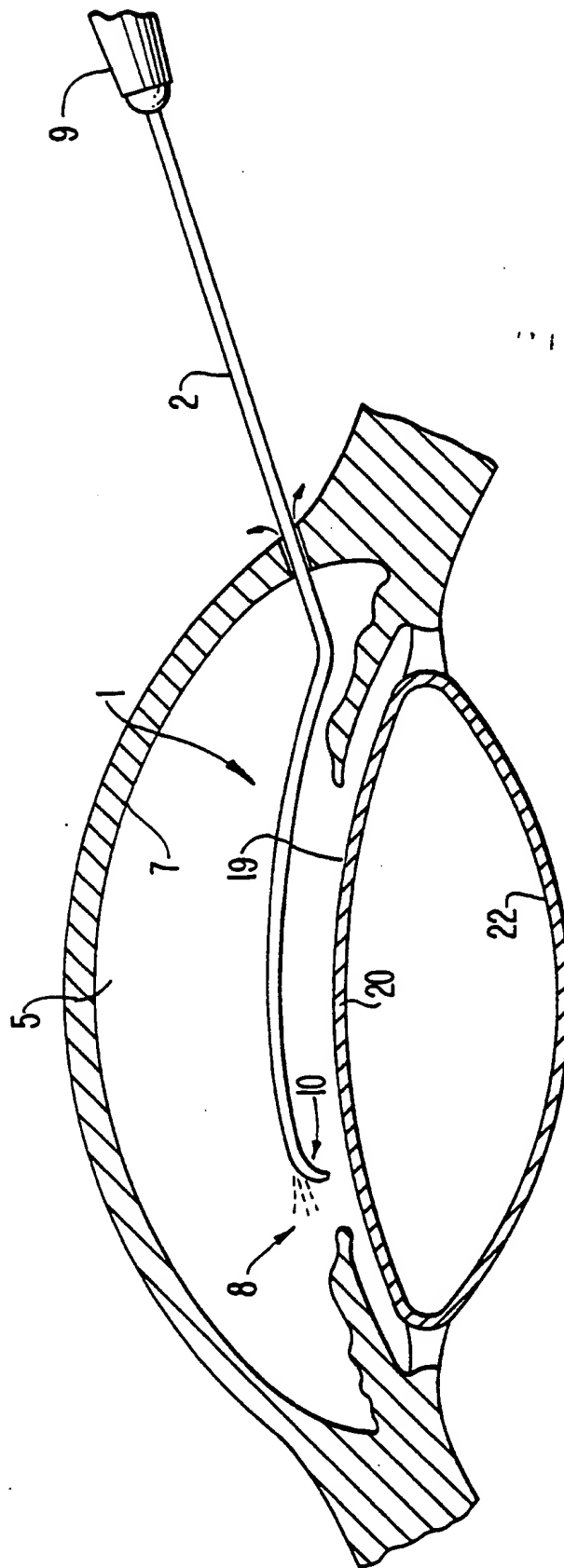


FIG. 4.



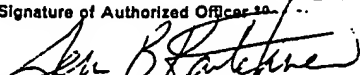
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FIG. 5.



INTERNATIONAL SEARCH REPORT

International Application No PCT/US85/02044

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ³			
According to International Patent Classification (IPC) or to both National Classification and IPC			
Int Cl ⁴	A61B 17/32; A61B 17/20		
US Cl	128/305; 604/22		
II. FIELDS SEARCHED			
Minimum Documentation Searched ⁴			
Classification System	Classification Symbols		
US	128/305, 303R, 24A 604/19, 22, 35		
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵			
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴			
Category *	Citation of Document, ¹⁵ with Indication, where appropriate, of the relevant passages ¹⁷		Relevant to Claim No. ¹⁸
X,P	US, A, 4,526,571	02 July 1985 (WUCHINICH) See entire patent.	1-3, 6, 9-10, 12-13
Y	US, A, 3,589,363	29 June 1971 (BANKO) See Figures 5F-I and column 7, line 56 through column 8, line 35.	1-18
Y	Fibra-Sonics, Inc., 1977 catalog, (4 pages), 'The G-15E/RAIIA Lens Fragmentator/Aspirator', See especially Figures 3-8 of the fourth page.		1-18
A	US, A, 3,670,733	20 June 1972 (CARLISLE)	
A,P	US, A, 4,530,359	23 July 1985 (HELFGOTT et al)	
A,P	US, A, 4,515,583	07 May 1985 (SORICH)	
<p>* Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>			
IV. CERTIFICATION			
Date of the Actual Completion of the International Search ²		Date of Mailing of this International Search Report ³	
09 September 1985		07 JAN 1986	
International Searching Authority ¹		Signature of Authorized Officer ¹⁰	
ISA/US			

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No ¹⁸
A,P	US, A, 4,501,274	26 February 1985 (SKJAERPE)
A,P	US, A, 4,535,759	20 August 1985 (POLK et al)